

JUN 29 2000

K001443

510(k) Summary of Safety and Effectiveness

510(k) Submitter: Streck Laboratories, Inc
P.O. Box 45625
Omaha, Nebraska 68145

Correspondent: Paul Kittelson
Regulatory Affairs

Date Prepared: May 4, 2000

Names of Device:

Trade Name: Sugar-Chex One
Common Name: Glucose control solution
Classification Name: Quality control material (assayed and unassayed)
§862.1660

Predicate Device: Sugar Chex (K851042/A) manufactured
by Streck Laboratories

Description: Intended Use: Sugar Chex One is designed as a control material for verifying the performance of LifeScan Saturn Test Strips. It is intended to be used by diabetic patients. A set of product consists of a polyethylene bottle containing 2 mL aqueous mixture and a dropper tip. It is packaged in a card board box with a package insert. The aqueous suspension consists of a preservative solution, bovine blood components and glucose.

Comparison with Predicate Device: Sugar Chex One is comparable to Sugar Chex(K851042/A) in that both products are glucose control solutions for verifying performance of glucose measurement methods that are based on Strip technologies. Sugar Chex One differs from Sugar Chex largely by the fact that it is designed and assayed for LifeScan Saturn Test Strips manufactured by LifeScan, Inc., Milpitas, CA. Sugar Chex is assayed for glucose monitoring systems made by several companies.

Discussion of Tests and Test Results: Studies were conducted on four (4) Pilot lots to assess the performance of Sugar Chex One. Product stability (shelf life) was established by analysis at intervals over 6 months. Open vial stability testing, simulating "user" conditions, was conducted for 60 days with acceptable results.
Acceptable product performance on 3 separate Lots of LifeScan Saturn Test Strips was confirmed.

Conclusions Drawn from Tests: Sugar Chex One is an effective control for monitoring the performance of LifeScan Saturn Test Strips when used according to instructions in the package insert.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 29 2000

Mr. Paul Kittelson
Quality Assurance/Regulatory Affairs
Streck Laboratories, Inc.
14124 Industrial Road
Omaha, Nebraska 68144

Re: K001443
Trade name: Sugar-Chex One
Regulatory Class: I reserved
Product Code: JJX
Dated: June 14, 2000
Received: June 22, 2000

Dear Mr. Kittelson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

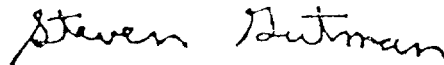
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large, stylized 'S' and 'G'.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INTENDED USE STATEMENT

March 30, 2000

510(k) Number (if known): K001443
~~To be assigned~~

Device Name: Sugar-Chex One

Intended Use:

Sugar-Chex One is a liquid glucose control product intended for use with LifeScan Saturn Test Strips. It is defined as a Quality Control Material in CFR § 862.1660 and is intended to be used by diabetic patients to provide assurance that the Saturn Test Strip is functioning properly and producing accurate glucose concentration information.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001443

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21CFR 801.109)

OR

Over-The-Counter Use ✓
(Optional format 1-2-96)

Streck Laboratories, Inc

510(k) Sugar-Chex One